

Technical Specification
Product: Purelay®-Pharm FG-100E

<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
1.0 Description	polypropylene-sheet (PP) for pharmaceutical packaging			
2.0 Dimensions				
2.1 Sheet thickness	DIN 53 370	µm	300 - 800	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colours	-	-	1. <i>clear (not coloured)</i> 2. <i>white opaque</i>	
2.4 Density	DIN EN ISO 118-3	g/cm ³	0.90 - 0.92	
2.5 Materials	PP-homopolymer: raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
3.0 Thermal Properties				
3.1 Melt Flow Index (MFI)	DIN EN ISO 1133 (230° / 2,16 kg)	g/10min	4.5	± 1.5
3.2 Crystalline melting point	ISO 11357-3	°C	162	± 3
3.3 Shrinkage (machine & cross dir.)	internal (140°/20min)	%	+1 to -2	
4.0 Mechanical Properties				
4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
Colour:	according to reference			
Gloss:	outer surfaces glossy			

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6.0 Permeability (sheet thickness 300 µm)				
6.1 WVTR	Lyssy *) (38°/90-0% RH)	g/m ² ·d	< 0.4	
6.2 OTR	DIN 53 380 (23°/0% RH)	cm ³ /m ² ·d·bar	< 300	
7.0 Reel format				
Core: inner diameter		mm	76	± 1
thickness		mm	8	
Reel: outer diameter		mm	max. 750	
8.0 Labelling				
Reel:	reel labels on the sheet and in the core			
Pallets:	pallets labelled on the side and on the front end			
9.0 Packaging				
Reel:	packed dustproof in PE-liner			
Pallets:	Europallets 800 x 1200 mm, clean, dry, in good condition			
10.0 Storage				
	recommended: dry conditions; 18 - 28 °C; 40 - 65 % RH			
	Shelf life: 12 months (based at production date)			
11.0 Production & Documentation				
	- production in clean room (US Fed Std. 209 E; 100 000) and according to GMP-regulations			
	- documentation: Certificate of Analysis; roll distribution diagram			
	- production according to Quality-Management-System ISO 9001			

*) Tested at Bayer Lab, Leverkusen.

prepared: Mr. Dr. Haas	approved: Mr. Kriegler	valid until: 31-Dec-2013	date: 01-Jan-2013 page: 2 of 2
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<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
1.0 Description	polypropylene-sheet (PP) for pharmaceutical packaging			
2.0 Dimensions				
2.1 Sheet thickness	DIN 53 370	µm	250	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>clear (not coloured)</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
3.0 Thermal Properties				
3.1 Melt Flow Index (MFI)	DIN EN ISO 1133 (230° / 2,16 kg)	g/10min	4.5	± 1.5
3.2 Crystalline melting point	ISO 11357-3	°C	162	± 3
3.3 Shrinkage (machine & cross dir.)	internal (140°/20min)	%	+1 to -2	
4.0 Mechanical Properties				
4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 90	
5.2 Haze	ASTM D-1003	%	< 17	

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6.0 Permeability				
6.1 WVTR	Lyssy (38°/90-0% RH)	g/m ² ·d	< 0.5	
6.2 OTR	DIN 53 380 (23°/0% RH)	cm ³ /m ² ·d·bar	< 400	
7.0 Reel format				
Core: inner diameter		mm	76	± 1
thickness		mm	8	
Reel: outer diameter		mm	max. 750	
8.0 Labelling				
Reel:	reel labels on the sheet and in the core			
Pallets:	pallets labelled on the side and on the front end			
9.0 Packaging				
Reel:	packed dustproof in PE-liner			
Pallets:	Europallets 800 x 1200 mm, clean, dry, in good condition			
10.0 Storage	recommended: dry conditions; 18 - 28 °C; 40 - 65 % RH			
11.0 Production & Documentation	<ul style="list-style-type: none"> - production in clean room (US Fed Std. 209 E; 100 000) and according to GMP-regulations - documentation: Certificate of Analysis; roll distribution diagram - production according to Quality-Management-System ISO 9001 			

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2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>clear (not coloured)</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
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3.3 Shrinkage (machine & cross dir.)	internal (140°/20min)	%	+1 to -2	
4.0 Mechanical Properties				
4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 90	
5.2 Haze	ASTM D-1003	%	< 17	

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1.0 Description	polypropylene-sheet (PP) for pharmaceutical packaging			
2.0 Dimensions				
2.1 Sheet thickness	DIN 53 370	µm	300	± 5 %
2.2 Sheet width	-	mm	to customer order	± 0.5
2.3 Colour	-	-	red	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
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5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 90	

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2.2 Sheet width	-	mm	to customer order	± 0.5
2.3 Colour	-	-	clear (not coloured)	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
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4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 90	
5.2 Haze	ASTM D-1003	%	< 18	

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2.1 Sheet thickness	DIN 53 370	µm	300	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>white opaque</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.92	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
3.0 Thermal Properties				
3.1 Melt Flow Index (MFI)	DIN EN ISO 1133 (230° / 2,16 kg)	g/10min	4.5	± 1.5
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4.0 Mechanical Properties				
4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 90	

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6.0 Permeability				
6.1 WVTR	Lyssy *) (38°/90-0% RH)	g/m ² ·d	< 0.4	
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Reel: outer diameter		mm	max. 750	
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1.0 Description	polypropylene-sheet (PP) for pharmaceutical packaging			
2.0 Dimensions				
2.1 Sheet thickness	DIN 53 370	µm	350	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>clear (not coloured)</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
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4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 90	
5.2 Haze	ASTM D-1003	%	< 25	

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6.0 Permeability				
6.1 WVTR	Lyssy (38°/90-0% RH)	g/m ² ·d	< 0,25	
6.2 OTR	DIN 53 380 (23°/0% RH)	cm ³ /m ² ·d·bar	< 250	
7.0 Reel format				
Core: inner diameter		mm	76	± 1
thickness		mm	8	
Reel: outer diameter		mm	max. 750	
8.0 Labelling				
Reel:	reel labels on the sheet and in the core			
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2.1 Sheet thickness	DIN 53 370	µm	350	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>white opaque</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.92	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
3.0 Thermal Properties				
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1.0 Description	polypropylene-sheet (PP) for pharmaceutical packaging			
2.0 Dimensions				
2.1 Sheet thickness	DIN 53 370	µm	400	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>clear (not coloured)</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
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4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 90	
5.2 Haze	ASTM D-1003	%	< 35	

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2.1 Sheet thickness	DIN 53 370	µm	500	± 5 %
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2.3 Colour	-	-	clear (not coloured)	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
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4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 85	
5.2 Haze	ASTM D-1003	%	< 50	

Technical Specification
Product: PURELAY®-Pharm FG-100E

<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
6.0 Permeability				
6.1 WVTR	DIN 53 122/2 (38°/90-0% RH)	g/m ² ·d	< 0.2	
6.2 OTR	DIN 53 380 (23°/0% RH)	cm ³ /m ² ·d·bar	< 200	
7.0 Reel format				
Core: inner diameter		mm	76	± 1
thickness		mm	8	
Reel: outer diameter		mm	max. 750	
8.0 Labelling				
Reel:	reel labels on the sheet and in the core			
Pallets:	pallets labelled on the side and on the front end			
9.0 Packaging				
Reel:	packed dustproof in PE-liner			
Pallets:	Europallets 800 x 1200 mm, clean, dry, in good condition			
10.0 Storage				
	recommended: dry conditions; 18 - 28 °C; 40 - 65 % RH			
	Shelf life: 12 months (based at production date)			
11.0 Production & Documentation				
	- production in clean room (US Fed Std. 209 E; 100 000) and according to GMP-regulations			
	- documentation: Certificate of Analysis; roll distribution diagram			
	- production according to Quality-Management-System ISO 9001			

Technical Specification
Product: PURELAY®-Pharm FG-100E

<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
1.0 Description	polypropylene-sheet (PP) for pharmaceutical packaging			
2.0 Dimensions				
2.1 Sheet thickness	DIN 53 370	µm	600	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>clear (not coloured)</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
3.0 Thermal Properties				
3.1 Melt Flow Index (MFI)	DIN EN ISO 1133 (230° / 2,16 kg)	g/10min	4.5	± 1.5
3.2 Crystalline melting point	ISO 11357-3	°C	162	± 3
3.3 Shrinkage (machine & cross dir.)	intern (140°/20min)	%	+1 to -2	
4.0 Mechanical Properties				
4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 85	
5.2 Haze	ASTM D-1003	%	< 55	

prepared: Mr. Dr. Haas	approved: Mr. Kriegler	valid until: 31-Dec-2013	date: 01-Jan-2013 page: 1 of 2
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Technical Specification
Product: PURELAY®-Pharm FG-100E

<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
6.0 Permeability				
6.1 WVTR	DIN 53 122/2 (38°/90-0% RH)	g/m ² ·d	< 0.2	
6.2 OTR	DIN 53 380 (23°/0% RH)	cm ³ /m ² ·d·bar	< 130	
7.0 Reel format				
Core: inner diameter		mm	76	± 1
thickness		mm	8	
Reel: outer diameter		mm	max. 750	
8.0 Labelling				
Reel:	reel labels on the sheet and in the core			
Pallets:	pallets labelled on the side and on the front end			
9.0 Packaging				
Reel:	packed dustproof in PE-liner			
Pallets:	Europallets 800 x 1200 mm, clean, dry, in good condition			
10.0 Storage				
	recommended: dry conditions; 18 - 28 °C; 40 - 65 % RH			
	Shelf life: 12 months (based at production date)			
11.0 Production & Documentation				
	- production in clean room (US Fed Std. 209 E; 100 000) and according to GMP-regulations			
	- documentation: Certificate of Analysis; roll distribution diagram			
	- production according to Quality-Management-System ISO 9001			

Technical Specification
Product: PURELAY®-Pharm FG-100E

<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
1.0 Description	polypropylene-sheet (PP) for pharmaceutical packaging			
2.0 Dimensions				
2.1 Sheet thickness	DIN 53 370	µm	700	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>clear (not coloured)</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
3.0 Thermal Properties				
3.1 Melt Flow Index (MFI)	DIN EN ISO 1133 (230° / 2,16 kg)	g/10min	4.5	± 1.5
3.2 Crystalline melting point	ISO 11357-3	°C	162	± 3
3.3 Shrinkage (machine & cross dir.)	internal (140°/20min)	%	+1 to -2	
4.0 Mechanical Properties				
4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 85	
5.2 Haze	ASTM D-1003	%	< 60	

Technical Specification
Product: PURELAY®-Pharm FG-100E

<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
6.0 Permeability				
6.1 WVTR	Lyssy (38°/90-0% RH)	g/m ² ·d	< 0.20	
6.2 OTR	DIN 53 380 (23°/0% RH)	cm ³ /m ² ·d·bar	< 130	
7.0 Reel format				
Core: inner diameter		mm	76	± 1
thickness		mm	8	
Reel: outer diameter		mm	max. 750	
8.0 Labelling				
Reel:	reel labels on the sheet and in the core			
Pallets:	pallets labelled on the side and on the front end			
9.0 Packaging				
Reel:	packed dustproof in PE-liner			
Pallets:	Europallets 800 x 1200 mm, clean, dry, in good condition			
10.0 Storage	recommended: dry conditions; 18 - 28 °C; 40 - 65 % RH Shelf life: 12 months (based at production date)			
11.0 Production & Documentation	<ul style="list-style-type: none"> - production in clean room (US Fed Std. 209 E; 100 000) and according to GMP-regulations - documentation: Certificate of Analysis; roll distribution diagram - production according to Quality-Management-System ISO 9001 			

prepared: Mr. Dr. Haas	approved: Mr. Kriegler	valid until: 31-Dec-2013	date: 01-Jan-2013 page: 2 of 2
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Technical Specification
Product: PURELAY®-Pharm FG-100E

<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
1.0 Description	polypropylene-sheet (PP) for pharmaceutical packaging			
2.0 Dimensions				
2.1 Sheet thickness	DIN 53 370	µm	800	± 5 %
2.2 Sheet width	-	mm	<i>to customer order</i>	± 0.5
2.3 Colour	-	-	<i>clear (not coloured)</i>	
2.4 Density	DIN EN ISO 1183-3	g/cm ³	0.90	± 0.01
2.5 Materials	PP-homopolymer raw materials used meet the corresponding requirements of the EC and FDA-regulations for pharmaceutical packaging			
3.0 Thermal Properties				
3.1 Melt Flow Index (MFI)	DIN EN ISO 1133 (230° / 2,16 kg)	g/10min	4.5	± 1.5
3.2 Crystalline melting point	ISO 11357-3	°C	162	± 3
3.3 Shrinkage (machine & cross dir.)	internal (140°/20min)	%	+1 to -2	
4.0 Mechanical Properties				
4.1 Tensile strength (machine & cross dir.)	DIN EN ISO 527-3	N/mm ²	> 30	
4.2 Elongation at break (machine & cross dir.)	DIN EN ISO 527-3	%	> 1000	
5.0 Optical Properties				
5.1 Gloss	DIN 67 530	%	> 85	
5.2 Haze	ASTM D-1003	%	< 65	

Technical Specification
Product: PURELAY®-Pharm FG-100E

<i>Properties</i>	<i>Test method</i>	<i>Unit</i>	<i>Value</i>	<i>Tolerance</i>
6.0 Permeability				
6.1 WVTR	DIN 53 122/2 (38°/90-0% RH)	g/m ² ·d	< 0.2	
6.2 OTR	DIN 53 380 (23°/0% RH)	cm ³ /m ² ·d·bar	< 130	
7.0 Reel format				
Core: inner diameter		mm	76	± 1
thickness		mm	8	
Reel: outer diameter		mm	max. 750	
8.0 Labelling				
Reel:	reel labels on the sheet and in the core			
Pallets:	pallets labelled on the side and on the front end			
9.0 Packaging				
Reel:	packed dustproof in PE-liner			
Pallets:	Europallets 800 x 1200 mm, clean, dry, in good condition			
10.0 Storage				
	recommended: dry conditions; 18 - 28 °C; 40 - 65 % RH			
	Shelf life: 12 months (based at production date)			
11.0 Production & Documentation				
	- production in clean room (US Fed Std. 209 E; 100 000) and according to GMP-regulations			
	- documentation: Certificate of Analysis; roll distribution diagram			
	- production according to Quality-Management-System ISO 9001			